Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of sodium valproate and Levetiracetam on the prevention of migraine headaches

Protocol summary

Study aim
Comparison of the effect of sodium valproate and Levetiracetam on the prevention of migraine headaches on patients referred to Emam Ali Clinics of Shahrekord in 1397.

Design
A clinical trial without a parallel control group, single-blind, randomized

Settings and conduct
After considering the entry and exit criteria, 80 migraine patients referred to Imam Ali Shahrekord clinic were randomly assigned to one of two groups: sodium valproate or Levetiracetam. Patients were allowed to take 500 mg of acetaminophen if they had mild and severe pain and lasted for 8 hours. The routine treatment for both groups was 80 mg/day of propranolol.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 65 years old; Migraine headache history for at least 6 months before study based on IHS criteria; Moderate to the severe headache for less than 6 days with Visual Analogue Scale; Natural Signs and Natural Nerve Findings; Exclusion criteria: Patients with kidney failure, liver disease, heart disease, active stomach ulcer disease or diabetes or abnormal vital symptoms; Allergy to valproate and Levetiracetam; Pregnant or lactating women; Cases of other types of headaches such as sinus headaches; Taking nonsteroidal anti-inflammatory drugs within 24 hours or valproate over the past 2 weeks

Intervention groups
Patients are divided into two intervention groups. One of the two groups is sodium valproate and the other group is receiving Levetiracetam

Main outcome variables
Headache severity; Number of headaches per month

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171030037093N14**
Registration date: **2019-07-02, 1398/04/11**
Registration timing: **prospective**

Last update: **2019-07-02, 1398/04/11**
Update count: **0**

Registration date
2019-07-02, 1398/04/11

Registrant information

Name
Sadra Ansaripour

Name of organization / entity
Shahrekord University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3650 3487

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st_ansari.s@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of sodium valproate and Levetiracetam on the prevention of migraine headaches

Public title
Evaluation of the effect of sodium valproate and Levetiracetam on the prevention of migraine headaches
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years old Migraine headache history for at least 6 months before study based on IHS criteria Moderate to severe headache for less than 6 days with Visual Analogue Scale Natural Signs and Natural Nerve Findings.
Exclusion criteria:
Patients with kidney failure, liver disease, heart disease, active stomach ulcer disease or diabetes or abnormal vital symptoms Allergy to valproate and Levetiracetam Pregnant or lactating women Cases of other types of headaches such as sinus headaches Taking nonsteroidal anti-inflammatory drugs within 24 hours or valproate over the past 2 weeks
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to one of the two groups by selecting the cards named A and B.
Blinding (investigator's opinion)
Single blinded
Blinding description
The drugs were coded without any tags, and the patient randomly selected one of two drugs by choosing the code, and the name of each individual and the prescription drug code was recorded by the clerk. The patient did not have any type of drug
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713492
Approval date
2018-07-22, 1397/04/31
Ethics committee reference number
IR.SKUMS.REC.1397.138

Health conditions studied

1

Description of health condition studied
migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Headache severity
Timepoint
Before the start of the study, notes were taken every 30 days
Method of measurement
Based on VAS and doctor

2

Description
Number of headaches per month
Timepoint
Before the start of the study, notes were taken every 30 days
Method of measurement
MIDAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group received 500 mg of levetiracetam per day
Category
Treatment - Drugs

2

Description
Intervention group: The second group received 500 mg/day sodium sulfate.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Clinic
Full name of responsible person
Narges Maleki
Street address
Shariati Blvd., Imam Ali Clinic
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Chahar-Mahal-va-Bakhtiari
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8816788640
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Dr.safari@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr. seyed Kamal Solati(Associate Professor of Psychology)
Street address
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd
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8815713471
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Email
kamal_solati@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mohammadhosein Saffari
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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Person responsible for updating data

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Information about the main outcome can be shared.

When the data will become available and for how long
Start the access period 4 months after publishing the results

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Use data to complete clinical trial studies

From where data/document is obtainable
Imam Ali Hospital

What processes are involved for a request to access data/document
After the investigation of researcher request and presentation of required documents will

Comments